## REMARKS

Entry of the above amendments and reconsideration of this application are respectfully requested. Upon entry of the amendments this application will contain claims 1-22 pending and under consideration.

# Amendments

The specification has been amended above to recite subject matter incorporated by reference. In particular, U.S. Patent Nos. 5,047,231 and 6,223,693 are cited at page 8, and are expressly incorporated by reference into the application (see express incorporation by reference at page 15, lines 4-8). These U.S. Patents are cited for their teachings as to ways to prepare rawhide products, and both of them teach preparative methods as set forth in the amendment to the specification above. Accordingly, this amendment introduces no new subject matter.

The claims have been amended for the purpose of expediting the prosecution of the application. The amendments to the claims are supported, for example, as follows:

Claim	Support		
1	page 9, line 30; page 7, line 20; page 8, lines 6-7; paragraph beginning at page 8, line 11; paragraph beginning at page 9, line 18		
2	page 9, line 30; page 5, lines 4-6; Example 2		
3	page 9, line 30; page 8, lines 6-7		
4	page 9, line 30		
5	page 9, line 30		
6	page 9, line 30		
7	page 9, line 30		
8	page 9, line 30; page 5, lines 4-6; Example 2		
9	page 9, line 30; page 5, lines 4-6; Example 2		
10	page 9, line 30; page 5, lines 4-6; Example 2		
11	page 9, line 30		
12	page 9, line 30; page 7, line 20; page 8, lines		
	6-7; paragraph beginning at page 8, line 11;		
	paragraph beginning at page 9, line 18		
13	page 9, line 30; paragraph beginning at page 8, line 11		
14	page 5, lines 4-6; Example 2		
<sup>15</sup>	page 5, lines 4-6; Example 2		
16	page 9, line 30; page 7, line 20; page 8, lines		
•	6-7; paragraph beginning at page 8, line 11;		
	paragraph beginning at page 9, line 18		
17	page 8, lines 26-34		
18	paragraph beginning at page 9, line 1		
19	page 8, lines 26-34		
20	page 5, lines 4-6; Example 2		
21	page 5, lines 4-6; Example 2		
22	page 9, line 30; paragraph beginning at page 9, line 1		

Accordingly, no new matter is introduced by the amendments to the claims.

# Interview

The undersigned attorney would like to thank Examiner Sayala for the courtesies extended in the interview dated May 21, 2008. In the interview, Witt reference was

discussed as being important to maintaining a rejection of the claims. The Examiner indicated that additional distinctions from the Witt reference should be explored, including the possibility of claims that emphasize the efficacy of sodium tripolyphosphate and cetyl pyridinium chloride to achieve the claimed effects, and claims that exclude the presence of chlorite (as in Witt et al.). That has been done, and additional distinctions are presented and discussed with this Response.

Turning now to the rejections outstanding, claims 1-22 stand rejected under 35 USC § 103(a) as being unpatentable over Spanier et al. (US Patents 5011679 and 5114704) in view of Witt et al. (US Patent 6350438) and further in view of Perlberg et al. (US Patent 6223693). For the reasons detailed below, it is submitted that this rejection would be in error to the extent maintained against the amended claims.

Claims 1-22 of the application, as amended, are directed to dog chew products, articles, or methods, that include or involve an ingestible rawhide substrate with cetyl pyridinium chloride and sodium tripolyphosphate incorporated on or in the ingestible rawhide substrate. As further requirements of the claims as amended, the "cetyl

Amendment and Reply to Office Action Serial No. 10/623,145 George K. Stookey Document No. #541240 Page 10 of 18 pyridinium chloride and sodium tripolyphosphate are incorporated in amounts wherein the cetyl pyridinium chloride and sodium tripolyphosphate are together effective to reduce the incidence of gingivitis, dental calculus and breath malodor in a dog that chews the dried dog chew product." Thus, as required by the claims, these two additives together, even in the absence of any other additives, must be "effective to reduce the incidence of gingivitis, dental calculus and breath malodor in a dog that chews the dried dog chew product". The claims thus now emphasize the efficacy of the sodium tripolyphosphate and cetyl pyridinium chloride.

In order for the current rejection of these claims to be proper, the cited prior art must, among other things, provide a reasonable expectation of success for the subject matter as claimed. In re Pantzer et al., 144 U.S.P.Q. 415 (CCPA 1965); In re Longi et al., 225 U.S.P.Q. 645 (CAFC 1985). Further, the courts have long recognized that low levels of predictability exist in arts involving chemical reactions and physiological activity. In re: Fisher, 166 U.S.P.Q. 18 (CCPA 1970); In re Hogan et al., 194 U.S.P.Q. 527 (CCPA 1977). Relatedly, obviousness determinations must be performed without "entry into the 'tempting but

Amendment and Reply to Office Action Serial No. 10/623,145 George K. Stookey Document No. #541240 Page 11 of 18 forbidden zone of hindsight.'" In re: Dembiczak, 50
U.S.P.Q. 2d at 1616 (Fed. Cir. 1999). Taking these
standards into account, the combination of references
relied upon in the Office Action does not support a proper
rejection under 35 USC § 103.

Example 2, beginning at page 12 of the application, describes a clinical study in which rawhide chew products incorporating the combination of sodium tripolyphosphate and cetyl pyridinium chloride were demonstrated to provide improved oral health including reductions in gingivitis and dental calculus (see Table 2, page 14, and comments thereon). The claims of the application have now all been amended to provide that as incorporated in the dog chew product, the cetyl pyridinium salt and sodium tripolyphosphate are "together effective to reduce the incidence of gingivitis, dental calculus and breath malodor in a dog that chews the dog chew product". These efficacies from the CPC/STP combination could not have been reasonably expected by one of ordinary skill in the art prior to the Applicant's discovery.

In this regard, the Examiner's attention is directed to the Declaration of Dr. George K. Stookey previously filed.

Dr. Stookey has researched in dental health for over four

Amendment and Reply to Office Action Serial No. 10/623,145 George K. Stookey Document No. #541240 Page 12 of 18 decades, and has had a focus in researching systems for improving the dental health of companion animals, such as dogs and cats, for over two decades. He has authored or coauthored hundreds of papers appearing in scientific journals, as noted in his biographic information available at <a href="http://www.iusd.iupui.edu/depts/PCD/Faculty\_Listing/Stookey.htm.">http://www.iusd.iupui.edu/depts/PCD/Faculty\_Listing/Stookey.htm.</a>

As averred by Dr. Stookey, at the filing date of this application, "...it would not have been possible to predict beforehand whether the incorporation of cetyl pyridinium chloride in the combination with STP in an animal chew product would provide a dental health benefit to animals." Dr. Stookey notes that none of the references cited in the current rejection describes any experiment in any animal. Dr. Stookey then goes on to cite examples from literature in which active agents (antimicrobial agents) that were known to be effective in other contexts were tried in animal chew products, but failed to demonstrate efficacy when tested on animals.

In particular, Dr. Stookey notes that hundreds of reports in the dental literature had documented the ability of topical rinses, solutions and gels containing chlorhexidine to reduce the formation of dental plaque, gingivitis and periodontal disease as well as the

Amendment and Reply to Office Action Serial No. 10/623,145 George K. Stookey Document No. #541240 Page 13 of 18 development of dental caries in humans. Numerous reports in the dental literature also indicated that the application of these same products (particularly solutions and gels containing chlorhexidine) to experimental animals (typically rats and dogs) results in similar dental heath benefits. However, the incorporation of chlorhexidine into pet chew products did not help, as noted by Rawlings et al., J. Vet. Dent. 15:129-134 (1998). Dr. Stookey also notes a report by Brown et al., J Vet Dent 22(1); 16-19 (2005), in which the addition of a proprietary (unidentified) natural antibiotic to a pet chew product similarly did not help.

Further, the primary references to Spanier et al. unwaveringly teach that it is the use of an inorganic pyrophosphate (delivering  $P_2O_7$ ) that is the target of their disclosures. That is the whole point of the inventions alleged in Spanier et al. Yet, the proposed combination of references effectively guts this core of the Spanier et al. references, proposing the substitution of a different compound, sodium polyphosphate, for the inorganic pyrophosphate. It is submitted that this proposed substitution which reverses the essential teaching of the primary references is not proper, and thus that the

Amendment and Reply to Office Action Serial No. 10/623,145 George K. Stookey Document No. #541240 Page 14 of 18 references cannot properly be combined as asserted in the Office Action.

Moreover, continued reliance upon the teachings of Witt et al., alone or combined with Spanier et al. and/or Perlberg et al., would be similarly flawed. The core teachings of the Witt et al. reference are to use a chlorite salt as the active agent to provide efficacy, particularly sodium chlorite. At the top of column 6, Witt et al. specifically state that "The present invention includes chlorite ion as an essential ingredient in the compositions and methods of the present invention" (emphasis added). Thus, a proper use or combination of the Witt et al. reference would involve the use of a chlorite salt such as sodium chlorite. In this regard, attached for the Examiner's review are (1) a Material Safety Data Sheet for dry sodium chlorite powder; and (2) an IMEP Submission for dry sodium chlorite powder. At page 1, the MSDS notes that the dry powder is "Highly Toxic", "Harmful if Swallowed", and "Toxic in contact with skin", among other hazards. At page 4, similar warnings are provided, including the warning that the dry powder is "extremely destructive to the tissue of the mucous membranes and upper respiratory tract". Also, at page 4, the MSDS notes that

Amendment and Reply to Office Action Serial No. 10/623,145 George K. Stookey Document No. #541240 Page 15 of 18 for stability reasons, contact of the product with organic materials should be avoided (rawhide is clearly an organic material). At page 2, the IMEP Submission warns that the powder "causes severe skin and eye irritation", among other warnings.

In the context of the above-noted properties, the Examiner will note that Witt et al. discloses a plethora of products in which the chlorite remains in a dilute solution. With specific reference to Example 13 of Witt, even in the case of preparing pet rawhide chips and toy ropes containing chlorite, Witt et al. teach:

Chlorite-containing pet rawhide chips and toy ropes are prepared by spraying with the oral spray of Example 12 (10-20 ml per item). The impregnated items are given to dogs immediately or stored in sealed plastic bags to remain moist.

Example 13, column 24 (emphasis added). Thus, Witt et al. make specific efforts to prevent their material from drying out. To the contrary, the present claimed invention is directed to dried rawhide chew products, and methods for their preparation and use. Thus, properly considered, the Witt et al. reference teaches away from the present claims, and its use alone or in combination with the other

Amendment and Reply to Office Action Serial No. 10/623,145 George K. Stookey Document No. #541240 Page 16 of 18 reference(s) to reject the amended claims under 35 U.S.C. § 103 would be improper.

The Examiner's attention is also directed in particular to dependent claims 5, 9, 15 and 21, which provide that cetyl pyridinium chloride is the only antimicrobial agent in or on the rawhide substrate. This excludes from these claims the presence of chlorite ions as an effective anti-microbial agent as taught in the Witt et al. reference (see e.g. Witt et al., col. 4, lines 31-43 describing anti-microbial effects of chlorite ions). These claims are patentably distinct from the applied combination of references for this additional reason.

# Conclusion

Amendments to the claims have been presented in order to expedite the prosecution of this application, and without prejudice or admission in respect of the previously claimed subject matter or remarks in the Action. In summary, the combination of references is not proper, fails to teach the combined elements of the amended claims absent the use of hindsight, and further fails to establish an expectation of success for the invention as claimed. For these reasons at least, it is submitted that the present claimed invention is not obvious over the proposed

Amendment and Reply to Office Action Serial No. 10/623,145 George K. Stookey Document No. #541240 Page 17 of 18 combination of references. Withdrawal of the rejection and allowance of this application containing claims 1-22 is therefore solicited.

# Request for Interview

The Applicant requests an opportunity for an interview of the Examiner if the Examiner believes that any objection or rejection could be maintained against the application as amended. The Examiner is requested to contact the undersigned attorney to arrange any such interview necessary.

Respectfully submitted,

B<sub>17</sub>

Kenneth A. Gandy

Reg. No. 33,386

Woodard, Emhardt, Moriarty,

McNett & Henry LLP

111 Monument Circle, Ste 3700 Indianapolis, Indiana 46204

(317) 634-3456

# << Principal Display Panel (IMEP Submission - Sodium Chlorite)>>

# Sodium Chlorite Powder

FOR MANUFACTURING, FORMULATING OR REPACKAGING
GUARANTEE: Sodium Chlorite 80%
REG. NO. 26534 PEST CONTROL PRODUCTS ACT
READ THE LABEL BEFORE USING





DANGER POISON

DANGER CORROSIVE TO EYES AND SKIN

NET CONTENTS: 5 - 150 kg

Registrant's Address:

S.C. Johnson and Son, Limited

1 Webster Street

Brantford, ON, Canada

N3T 5R1

Phone 1-800-267-7259

Manufacturer's Address:

Energia Aragonesis SA

Paceo de Recoletos 27

Madrid, Spain

28004

<Secondary Display Panel (IMEP Submission - Sodium Chlorite)>

# **DIRECTIONS FOR USE:**

To be used only in the manufacture of a pest control product solely for export from Canada.

# PRECAUTIONS:

KEEP OUT OF THE REACH OF UNAUTHORIZED PERSONNEL.

CAUSES SEVERE SKIN AND EYE IRRITATION. STRONG OXIDIZER. CONTACT WITH OTHER MATERIAL MAY CAUSE FIRE. CAN VIOLENTLY DECOMPOSE AT ELEVATED TEMPERATURES. HARMFUL IF INHALED OR SWALLOWED.

Wear long sleeved shirt and long pants, chemical resistant gloves, goggles or face shield, a chemical resistant apron and boots when handling this product. Wash hands thoroughly with soap and water after handling and before eating, drinking, smoking, and using the toilet. Remove contaminated clothing and wash before re-use. DO NOT WEAR contaminated clothing.

# FIRST AID:

IF SWALLOWED: DO NOT INDUCE VOMITING. If conscious, give plenty of water. Call a physician or poison control centre immediately.

IN CASE OF SKIN CONTACT: Brush off excess chemical and flush skin with plenty of cold water for at least 15 minutes. Remove contaminated clothing and shoes.

IN CASE OF EYE CONTACT: Flush eyes immediately with cold water for at least fifteen minutes keeping eyelids apart. Call a physician or poison control centre immediately.

IF INHALED: Remove to fresh air. Give oxygen if breathing is difficult. Call a physician or poison control centre immediately.

Take container, label or product name and Pest Control Product Registration Number with you when seeking medical attention.

# TOXICOLOGICAL INFORMATION:

Treat symptomatically

## **ENVIRONMENTAL HAZARDS:**

This product is highly toxic to aquatic invertebrates and moderately toxic to waterfowl. Do not contaminate lakes, ponds, rivers, streams, estuaries and oceans by direct application, cleaning of equipment or disposal of wastes. Do not discharge effluent that has been treated with chlorine dioxide generated by this product into these waters unless the effluent has been detoxified by suitable means such as waste treatment.

# **CHEMICAL HAZARDS:**

Strong oxidizing agent. Mix only into water. Contamination may start a chemical reaction with

generation of heat, liberation of hazardous gases (Chlorine dioxide: a poisonous, explosive gas), and possible fire and explosion. Avoid any contact with flame or burning material, such as a lighted cigarette. Do not contaminate with moisture. Do not use moist or damp utensils.

## STORAGE:

Do not contaminate water, food or feed by storage or disposal. Store in a well-ventilated area. Store in a tightly closed original container. Keep away from incompatible materials (especially acids), combustible materials and direct sunlight. Always keep covered when not in use.

# **DECONTAMINATION AND DISPOSAL:**

Canadian formulators using this product should dispose of unwanted active ingredient and containers in accordance with municipal or provincial regulations. For additional details and information on cleanup of spills, contact the provincial regulatory agency or the manufacturer.

# NOTICE TO USER:

This control product is to be used only in accordance with the directions on this label. It is an offence under the PEST CONTROL PRODUCTS ACT to use a control product under unsafe conditions.

## **NOTICE TO BUYER:**

Seller's guarantee shall be limited to the terms set out on the label and, subject thereto, the buyer assumes the risk to persons or property arising from the use or handling of this product, and accepts the products on that condition.

\*\*\*\*\*\*\*\*\*\*

This label transcript service is offered by the Pest Management Regulatory Agency to provide efficient searching for label information. This service and this information do not replace the official hard-copy label. The PMRA does not provide any guarantee or assurance that the information obtained through this service is accurate, current or correct, and is therefore not liable for any loss resulting, directly or indirectly, from reliance upon this service.

#### MATERIAL SAFETY DATA SHEET

Date Printed: 06/24/2008 Date Updated: 02/01/2006

Version 1.6

Section 1 - Product and Company Information

Product Name

SODIUM CHLORITE

Product Number

13422

Brand

RIEDEL

Company

Sigma-Aldrich

Address

3050 Spruce Street

SAINT LOUIS MO 63103 US

Technical Phone:

800-325-5832

Fax:

800-325-5052

Emergency Phone:

314-776-6555

Section 2 - Composition/Information on Ingredient

Substance Name SODIUM CHLORITE

CAS #

SARA 313

No

7758-19-2

Formula

ClHO2.Na

Synonyms

Alcide LD \* Chlorous acid, sodium salt (8CI,9CI)

\* Neo Silox D \* Textile \* Textone

RTECS Number:

VZ4800000

Section 3 - Hazards Identification

## EMERGENCY OVERVIEW

Oxidizing. Highly Toxic (USA) Toxic (EU).

Contact with combustible material may cause fire. Harmful if swallowed. Toxic in contact with skin. Contact with acids liberates very toxic gas. Causes burns.

HMIS RATING

HEALTH: 3

FLAMMABILITY: 0
REACTIVITY: 3

SPECIAL HAZARD(S): Oxidizer

NFPA RATING

HEALTH: 3

FLAMMABILITY: 0
REACTIVITY: 3

SPECIAL HAZARD(S): Oxidizer

For additional information on toxicity, please refer to Section 11.

Section 4 - First Aid Measures

## ORAL EXPOSURE

If swallowed, wash out mouth with water provided person is conscious. Call a physician.

## INHALATION EXPOSURE

If inhaled, remove to fresh air. If breathing becomes difficult,

## call a physician.

#### DERMAL EXPOSURE

In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. Call a physician.

## EYE EXPOSURE

In case of contact with eyes, flush with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Call a physician.

## Section 5 - Fire Fighting Measures

#### EXPLOSION HAZARDS

Container explosion may occur under fire conditions.

# FLASH POINT

N/A

#### EXPLOSION LIMITS

Lower: 7 %

#### AUTOIGNITION TEMP

N/A

## FLAMMABILITY

N/A

#### EXTINGUISHING MEDIA

Suitable: Carbon dioxide, dry chemical powder, or appropriate foam.

# FIREFIGHTING

Protective Equipment: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes. Specific Hazard(s): Emits toxic fumes under fire conditions. Contact with other material may cause fire. May accelerate combustion.

## Section 6 - Accidental Release Measures

# PROCEDURE TO BE FOLLOWED IN CASE OF LEAK OR SPILL Evacuate area.

## PROCEDURE(S) OF PERSONAL PRECAUTION(S)

Wear self-contained breathing apparatus, rubber boots, and heavy rubber gloves.

#### METHODS FOR CLEANING UP

Absorb on sand or vermiculite and place in closed containers for disposal. Ventilate area and wash spill site after material pickup is complete.

# Section 7 - Handling and Storage

## HANDLING

User Exposure: Do not breathe vapor. Do not get in eyes, on skin, on clothing. Avoid prolonged or repeated exposure.

#### STORAGE

Suitable: Keep tightly closed. Keep away from combustible

2

materials, heat, sparks, and open flame.

# SPECIAL REQUIREMENTS

Avoid contact with acid.

# Section 8 - Exposure Controls / PPE

## ENGINEERING CONTROLS

Use only in a chemical fume hood. Safety shower and eye bath.

# PERSONAL PROTECTIVE EQUIPMENT

Respiratory: Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU). Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Hand: Compatible chemical-resistant gloves.

Eye: Chemical safety goggles.

## GENERAL HYGIENE MEASURES

Wash thoroughly after handling. Remove and wash contaminated clothing promptly.

Appearance	Physical State: Color: White Form: Powder	Solid	
Property	Value	At Temperature or Pressure	
Molecular Weight pH	90.44 AMU 10.0 - 11.0	20 °C Concentration: 100 g/1	
BP/BP Range MP/MP Range Freezing Point Vapor Pressure Vapor Density Saturated Vapor Conc. SG/Density Bulk Density Odor Threshold Volatile% VOC Content Water Content Evaporation Rate Viscosity Surface Tension Partition Coefficient Decomposition Temp. Flash Point Explosion Limits Flammability Autoignition Temp Refractive Index Optical Rotation Miscellaneous Data Solubility	N/A		

# Section 10 - Stability and Reactivity

#### STABILITY

Stable: Stable.

Materials to Avoid: Strong reducing agents, Finely powdered metals, Phosphorus, Sulfur, Zinc, Ammonia, Organic materials, Acids, Amines.

HAZARDOUS DECOMPOSITION PRODUCTS

Hazardous Decomposition Products: Hydrogen chloride gas.

## HAZARDOUS POLYMERIZATION

Hazardous Polymerization: Will not occur

# Section 11 - Toxicological Information

## ROUTE OF EXPOSURE

Skin Contact: Causes burns.

Skin Absorption: Toxic if absorbed through skin.

Eye Contact: Causes burns.

Inhalation: May be harmful if inhaled. Material is extremely destructive to the tissue of the mucous membranes and upper

respiratory tract.

Ingestion: Harmful if swallowed.

#### SIGNS AND SYMPTOMS OF EXPOSURE

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated. Prolonged exposure may result in delayed lung injury.

#### TOXICITY DATA

Oral

Rat

165 mg/kg

LD50

Remarks: Liver: Jaundice, other or unclassified. Kidney, Ureter,

Bladder:Interstitial nephritis. Biochemical:Metabolism

(intermediary): Other.

Inhalation

Rat

230 mg/m3

LC50

Oral

Mouse

350 mg/kg

LD50

Oral

Guinea pig

300 mg/kg

LD50

Oral

Rat

350 mg/kg

LD50

4

### CHRONIC EXPOSURE - CARCINOGEN

Result: This product is or contains a component that is not classifiable as to its carcinogenicity based on its IARC, ACGIH, NTP, or EPA classification.

Species: Mouse

Route of Application: Oral

Dose: 29750 MG/KG Exposure Time: 85W

Frequency: C

Result: Liver: Tumors. Tumorigenic: Carcinogenic by RTECS criteria.

#### IARC CARCINOGEN LIST

Rating: Group 3

### CHRONIC EXPOSURE - TERATOGEN

Species: Rat
Dose: 800 MG/KG

Route of Application: Oral Exposure Time: (8-15D PREG)

Result: Effects on Embryo or Fetus: Fetotoxicity (except death,

e.g., stunted fetus).

Species: Rat
Dose: 80 MG/KG

Route of Application: Intraperitoneal

Exposure Time: (8-15D PREG)

Result: Effects on Embryo or Fetus: Fetotoxicity (except death,

e.g., stunted fetus).

## CHRONIC EXPOSURE - MUTAGEN

Species: Rat
Route: Oral
Dose: 84 MG/KG
Exposure Time: 12W

Mutation test: DNA inhibition

Species: Rat
Route: Oral
Dose: 660 MG/KG
Exposure Time: 66D
Mutation test: sperm

Species: Mouse

Route: Intraperitoneal

Dose: 15 MG/KG

Mutation test: Micronucleus test

Species: Hamster Dose: 20 MG/L

Cell Type: fibroblast

Mutation test: Cytogenetic analysis

## CHRONIC EXPOSURE - REPRODUCTIVE HAZARD

Species: Rat
Dose: 16 GM/KG

Route of Application: Oral

Exposure Time: (8-15D PREG)

Result: Effects on Fertility: Post-implantation mortality (e.g.,

dead and/or resorbed implants per total number of implants).

Species: Rat
Dose: 660 MG/KG

Route of Application: Oral Exposure Time: (66D MALE)

Result: Paternal Effects: Spermatogenesis (including genetic

material, sperm morphology, motility, and count).

Species: Rat
Dose: 1130 MG/KG

Route of Application: Oral

Exposure Time: (8W MALE/2W PRE-3W POST)

Result: Effects on Newborn: Biochemical and metabolic.

Species: Rat
Dose: 160 MG/KG

Route of Application: Intraperitoneal

Exposure Time: (8-15D PREG)

Result: Effects on Fertility: Post-implantation mortality (e.g.,

dead and/or resorbed implants per total number of implants).

Species: Mouse Dose: 22 GM/KG

Route of Application: Oral

Exposure Time: (1-21D PREG/28D POST)

Result: Effects on Newborn: Growth statistics (e.g., reduced

weight gain).

# Section 12 - Ecological Information

## ACUTE ECOTOXICITY TESTS

Test Type: EC50 Algae

Species: Selenastrum capricornutum resp.

Time: 96 h

Value: < 0.01 mg/l

Test Type: EC50 Daphnia Species: Daphnia magna

Time: 48 h

Value: 0.03 mg/l

Test Type: EC50 Daphnia Species: Daphnia magna

Time: 48 h

Value: 0.29 mg/1

Test Type: LC50 Fish

Species: Lepomis macrochirus (Bluegill)

Time: 96 h

Value: > 100 mg/l

Test Type: LC50 Fish

Species: Cyprinodon variegatus (Sheepshead minnow)

Time: 96 h
Value: 75 mg/l

Test Type: LC50 Fish

Species: Onchorhynchus mykiss (Rainbow trout)

Time: 96 h

Value: > 100 mg/l

Test Type: LC50 Fish

Species: Onchorhynchus mykiss (Rainbow trout)

Time: 96 h

Value: > 100 mg/l

ADDITIONAL RESULTS/DATA FROM RELEVENT SCIENTIFIC EXPERIMENTS

Avoid contamination of the environment

# Section 13 - Disposal Considerations

APPROPRIATE METHOD OF DISPOSAL OF SUBSTANCE OR PREPARATION

Contact a licensed professional waste disposal service to dispose of this material. Observe all federal, state, and local environmental regulations.

# Section 14 - Transport Information

#### DOT

Proper Shipping Name: Sodium chlorite

UN#: 1496 Class: 5.1

Packing Group: Packing Group II

Hazard Label: Oxidizer

PIH: Not PIH

#### IATA

Proper Shipping Name: Sodium chlorite

IATA UN Number: 1496 Hazard Class: 5.1 Packing Group: II

## Section 15 - Regulatory Information

## EU ADDITIONAL CLASSIFICATION

Symbol of Danger: O-T

Indication of Danger: Oxidizing. Toxic.

R: 8-22-24-32-34

Risk Statements: Contact with combustible material may cause fire. Harmful if swallowed. Toxic in contact with skin. Contact with acids liberates very toxic gas. Causes burns.

S: 17-26-36/37/39-45

Safety Statements: Keep away from combustible material. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Wear suitable protective clothing, gloves, and eye/face protection. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

## US CLASSIFICATION AND LABEL TEXT

Indication of Danger: Oxidizing. Highly Toxic (USA) Toxic (EU). Risk Statements: Contact with combustible material may cause fire. Harmful if swallowed. Toxic in contact with skin. Contact with acids liberates very toxic gas. Causes burns. Safety Statements: Keep away from combustible material. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Wear suitable protective clothing, gloves, and eye/face protection. In case of accident or if you feel unwell, seek medical advice immediately (show the label where

possible).

UNITED STATES REGULATORY INFORMATION

SARA LISTED: No

TSCA INVENTORY ITEM: Yes Yes

#### CANADA REGULATORY INFORMATION

WHMIS Classification: This product has been classified in accordance with the hazard criteria of the CPR, and the MSDS contains all the information required by the CPR.

DSL: Yes NDSL: No

# Section 16 - Other Information

#### DISCLAIMER

For R&D use only. Not for drug, household or other uses.

#### WARRANTY

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Inc., shall not be held liable for any damage resulting from handling or from contact with the above product. See reverse side of invoice or packing slip for additional terms and conditions of sale. Copyright 2008 Sigma-Aldrich Co. License granted to make unlimited paper copies for internal use only.